510 (K) Summary
In-Vision™ Imaging System

Date Prepared: January 2, 2003

Submitted by: JOMED Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Lorry W. Huffman
Regulatory Affairs Manager

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Device Name: In-Vision™ Imaging System

Classification name:	**Class**
892.1560 Ultrasonic pulsed echo imaging system	II

Predicate Device:
Cathscanner III Imaging System cleared under K944004 on May 4, 1995; ColorFlo Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K963290 on August 6, 1997; and the Resolve Option for the Oracle InVision Intravascular Ultrasound Imaging System cleared under K965223 on June 29, 1998.

JOMED Inc. purchased Endosonics Corporation under which K944004, K963290 and K965223 were filed.

Device Description:
The JOMED Inc. In-Vision™ Imaging System consists of the imaging catheter, the patient interface module, and the system console. The system console gathers and displays high-resolution intraluminal images that can be analyzed both qualitatively and quantitatively. In addition to supplying diagnostic information, the In-Vision™ Imaging Systems can be adjunct to interventional therapies, such as balloon angioplasty. With ChromoFlo™, a two-dimensional color map of relative blood flow is overlaid on the grayscale image, providing additional information for vessel analysis. The In-Line

Digital™ option displays a two-dimensional, 360° rotations, and longitudinal view of the vessel.

The imaging catheters are all marketed under separate 510(k)'s; Visions catheters K982329, Avanar catheters K000820, and Eagle Eye F/X 2.9F pending future submission.

Intended Use:
In-Vision™ Imaging System is used for the qualitative and quantitative evaluation of vascular morphology in the coronary arteries and vessels of the peripheral vasculature. It is also indicated as an adjunct to conventional angiographic procedures to provide an image of vessel lumen and wall structures.

ChromaFlo feature is indicated for qualitative blood flow information from peripheral and coronary vaculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

Device Technological Characteristics and Comparison to Predicate Device:
The In-Vision™ Imaging System uses the same fundamental scientific technology and has the same intended use and clinical applications as that of the predicate device. This is a software modification version upgrade to V4.1.

Performance Data:
Applicable testing was performed to evaluate the modifications to the In-Vision™ Imaging System. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:
The In-Vision™ Imaging System has the same *Intended Use* and utilizes the same *fundamental scientific technology* as that of the predicate devices. The performance data along with the *Declaration of Conformity with Design Controls* support a determination of substantial equivalence of the modified device, In-Vision™ Imaging System to the

predicate devices. This software modification version upgrade to V4.1 raises no new questions about safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2003

JOMED Inc.
c/o Ms. Lorraine W. Huffman
Regulatory Affairs Manager
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K031148
Trade Name: In-Vision™ Imaging System
Regulation Number: 21 CFR 870.2330
Regulation Name: Echocardiograph
Regulatory Class: Class II (two)
Product Code: DXK
Dated: April 8, 2003
Received: April 10, 2003

Dear Ms. Huffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031148

Device Name: In-Vision™ Imaging System

Indications for Use:

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ChromaFlo is indicated for qualitative blood flow information from peripheral and coronary vaculature; flow information can be an adjunct to other methods of estimating blood flow and blood perfusion.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.19)

OR

Over-the-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031148